# **Complete Summary**

#### **GUIDELINE TITLE**

Standards of medical care in diabetes. III. Detection and diagnosis of gestational diabetes mellitus (GDM).

### BIBLIOGRAPHIC SOURCE(S)

American Diabetes Association (ADA). Standards of medical care in diabetes. III. Detection and diagnosis of GDM. Diabetes Care 2006 Jan; 29(Suppl 1): S7.

#### **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: Standards of medical care in diabetes. III. Detection and diagnosis of gestational diabetes mellitus (GDM). Diabetes Care 2005 Jan; 28(suppl 1): S7.

# **COMPLETE SUMMARY CONTENT**

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

## **SCOPE**

# DISEASE/CONDITION(S)

Gestational diabetes mellitus

#### **GUIDELINE CATEGORY**

Diagnosis Risk Assessment Screening

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology

#### INTENDED USERS

Advanced Practice Nurses Allied Health Personnel Nurses Patients Physician Assistants Physicians

# GUIDELINE OBJECTIVE(S)

- To present recommendations for the detection and diagnosis of gestational diabetes mellitus (GDM)
- To provide clinicians, patients, researchers, payers, and other interested individuals with the components of diabetes care, treatment goals, and tools to evaluate the quality of care

#### TARGET POPULATION

Pregnant women with or at risk of developing gestational diabetes mellitus

#### INTERVENTIONS AND PRACTICES CONSIDERED

Risk Assessment and Diagnosis

- 1. Assessment of risk factors for gestational diabetes mellitus at the first prenatal visit
- 2. Plasma or serum glucose testing (fasting or casual)
- 3. One-step approach: diagnostic 100-g oral glucose tolerance test (OGTT) without prior plasma or serum glucose screening
- 4. Two-step approach: Initial screening by measuring the plasma or serum glucose concentration 1 hour after a 50-g oral glucose load (glucose challenge test [GCT]) followed by a 100-g diagnostic oral glucose tolerance test on that subset of women exceeding the glucose threshold value on the glucose challenge test

#### MAJOR OUTCOMES CONSIDERED

Predictive value of screening and diagnostic tests

#### METHODOLOGY

# METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

#### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

#### NUMBER OF SOURCE DOCUMENTS

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

American Diabetes Association's Evidence Grading System for Clinical Practice Recommendations

#### Α

Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial
- Evidence from a meta-analysis that incorporated quality ratings in the analysis
- Compelling non-experimental evidence (i.e., "all or none" rule developed by the Center for Evidence Based Medicine at Oxford\*)

Supportive evidence from well-conducted randomized, controlled trials that are adequately powered, including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

В

Supportive evidence from well-conducted cohort studies, including:

- Evidence from a well-conducted prospective cohort study or registry
- Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case-control study

С

<sup>\*</sup>Either all patients died before therapy and at least some survived with therapy, or some patients died without therapy and none died with therapy. Example: use of insulin in the treatment of diabetic ketoacidosis.

Supportive evidence from poorly controlled or uncontrolled studies, including:

- Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
- Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)
- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

Ε

Expert consensus or clinical experience

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendations have been assigned ratings of A, B or C, depending on the quality of evidence (see "Rating Scheme for the Strength of the Evidence"). Expert opinion (E) is a separate category for recommendations in which there is as yet no evidence from clinical trials, in which clinical trials may be impractical, or in which there is conflicting evidence. Recommendations with an "A" rating are based on large, well-designed clinical trials or well done meta-analyses. Generally, these recommendations have the best chance of improving outcomes when applied to the population to which they are appropriate. Recommendations with lower levels of evidence may be equally important but are not as well supported.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

#### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The recommendations were reviewed and approved October in 2005 by the Professional Practice Committee and, subsequently, by the Executive Committee of the Board of Directors.

#### RECOMMENDATIONS

#### MAJOR RECOMMENDATIONS

The evidence grading system for clinical practice recommendations (A through C, E) is defined at the end of the "Major Recommendations" field.

# <u>Detection and Diagnosis of Gestational Diabetes Mellitus (GDM)</u>

- Screen for diabetes in pregnancy using risk factor analysis and, if appropriate, use of an oral glucose tolerance test (OGTT). (C)
- Women with GDM should be screened for diabetes 6 to 12 weeks postpartum and should be followed up with subsequent screening for the development of diabetes or pre-diabetes. (E)

Risk assessment for GDM should be undertaken at the first prenatal visit. Women with clinical characteristics consistent with a high risk for GDM (those with marked obesity, personal history of GDM, glycosuria, or a strong family history of diabetes) should undergo glucose testing as soon as possible. A fasting plasma glucose (FPG)  $\geq$ 126 mg/dL or a casual plasma glucose  $\geq$ 200 mg/dL meets the threshold for the diagnosis of diabetes and needs to be confirmed on a subsequent day unless unequivocal symptoms of hyperglycemia are present. High-risk women not found to have GDM at the initial screening and average-risk women should be tested between 24 and 28 weeks of gestation. Testing should follow one of two approaches:

- One-step approach: perform a diagnostic 100-g OGTT
- Two-step approach: perform an initial screening by measuring the plasma or serum glucose concentration 1 hour after a 50-g oral glucose load (glucose challenge test) and perform a diagnostic 100-g OGTT on that subset of women exceeding the glucose threshold value on the glucose challenge test. When the two-step approach is used, a glucose threshold value ≥140 mg/dL identifies approximately 80% of women with GDM, and the yield is further increased to 90% by using a cutoff of ≥130 mg/dL.

Diagnostic criteria for the 100-g OGTT are as follows:  $\geq$ 95 mg/dL fasting,  $\geq$ 180 mg/dL at 1 hour,  $\geq$ 155 mg/dL at 2 hours, and  $\geq$ 140 mg/dL at 3 hours. Two or more of the plasma glucose values must be met or exceeded for a positive diagnosis. The test should be done in the morning after an overnight fast of 8 to 14 hours. The diagnosis can be made using a 75-g glucose load, but that test is not as well validated for detection of at-risk infants or mothers as the 100-g OGTT.

Low-risk status requires no glucose testing, but this category is limited to those women meeting all of the following characteristics:

- Age < 25 years
- Weight normal before pregnancy
- Member of an ethnic group with a low prevalence of GDM
- No known diabetes in first-degree relative.
- No history of abnormal glucose tolerance
- No history of poor obstetric outcome

# **Definitions**:

American Diabetes Association's Evidence Grading System for Clinical Practice Recommendations

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В

Supportive evidence from well-conducted cohort studies, including:

- Evidence from a well-conducted prospective cohort study or registry
- Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case-control study

C

Supportive evidence from poorly controlled or uncontrolled studies, including:

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- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

Ε

Expert consensus or clinical experience

CLINICAL ALGORITHM(S)

None provided

# EVIDENCE SUPPORTING THE RECOMMENDATIONS

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate detection and diagnosis of gestational diabetes mellitus (GDM)

POTENTIAL HARMS

Not stated

#### QUALIFYING STATEMENTS

## QUALIFYING STATEMENTS

- Evidence is only one component of decision-making. Clinicians care for
  patients, not populations; guidelines must always be interpreted with the
  needs of the individual patient in mind. Individual circumstances such as
  comorbid and coexisting diseases, age, education, disability, and, above all,
  patient's values and preferences must also be considered and may lead to
  different treatment targets and strategies. Also, conventional evidence
  hierarchies such as the one adapted by the American Diabetes Association
  may miss some nuances that are important in diabetes care.
- While individual preferences, comorbidities, and other patient factors may require modification of goals, targets that are desirable for most patients with diabetes are provided. These standards are not intended to preclude more

extensive evaluation and management of the patient by other specialists as needed.

# IMPLEMENTATION OF THE GUIDELINE

#### DESCRIPTION OF IMPLEMENTATION STRATEGY

In recent years, numerous health care organizations, ranging from large health care systems such as the U.S. Veteran's Administration to small private practices have implemented strategies to improve diabetes care. Successful programs have published results showing improvement in important outcomes such as A1C measurements and blood pressure and lipid determinations as well as process measures such as provision of eye exams. Successful interventions have been focused at the level of health care professionals, delivery systems, and patients. Features of successful programs reported in the literature include:

- Improving health care professional education regarding the standards of care through formal and informal education programs.
- Delivery of diabetes self-management education (DSME), which has been shown to increase adherence to standard of care.
- Adoption of practice guidelines, with participation of health care professionals
  in the process. Guidelines should be readily accessible at the point of service,
  such as on patient charts, in examining rooms, in "wallet or pocket cards," on
  personal digital assistants (PDAs), or on office computer systems. Guidelines
  should begin with a summary of their major recommendations instructing
  health care professionals what to do and how to do it.
- Use of checklists that mirror guidelines have been successful at improving adherence to standards of care.
- System changes, such as provision of automated reminders to health care professionals and patients, reporting of process and outcome data to providers, and especially identification of patients at risk because of failure to achieve target values or a lack of reported values.
- Quality improvement programs combining continuous quality improvement or other cycles of analysis and intervention with provider performance data.
- Practice changes, such as clustering of dedicated diabetes visits into specific times within a primary care practice schedule and/or visits with multiple health care professionals on a single day and group visits.
- Tracking systems either with an electronic medical record or patient registry have been helpful at increasing adherence to standards of care by prospectively identifying those requiring assessments and/or treatment modifications. They likely could have greater efficacy if they suggested specific therapeutic interventions to be considered for a particular patient at a particular point in time.
- A variety of non-automated systems, such as mailing reminders to patients, chart stickers, and flow sheets, have been useful to prompt both providers and patients.
- Availability of case or (preferably) care management services, usually by a nurse. Nurses, pharmacists, and other non-physician health care professionals using detailed algorithms working under the supervision of physicians and/or nurse education calls have also been helpful. Similarly dietitians using medical nutrition therapy (MNT) guidelines have been demonstrated to improve glycemic control.

 Availability and involvement of expert consultants, such as endocrinologists and diabetes educators.

Evidence suggests that these individual initiatives work best when provided as components of a multifactorial intervention. Therefore, it is difficult to assess the contribution of each component; however, it is clear that optimal diabetes management requires an organized, systematic approach and involvement of a coordinated team of health care professionals.

# IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

**IOM CARE NEED** 

Living with Illness Staying Healthy

IOM DOMAIN

Effectiveness

# IDENTIFYING INFORMATION AND AVAILABILITY

## BIBLIOGRAPHIC SOURCE(S)

American Diabetes Association (ADA). Standards of medical care in diabetes. III. Detection and diagnosis of GDM. Diabetes Care 2006 Jan; 29(Suppl 1): S7.

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

#### DATE RELEASED

1986 (revised 2006 Jan)

#### GUI DELI NE DEVELOPER(S)

American Diabetes Association - Professional Association

SOURCE(S) OF FUNDING

The American Diabetes Association (ADA) received an unrestricted educational grant from LifeScan, Inc., a Johnson and Johnson Company, to support publication of the 2006 Diabetes Care Supplement.

#### GUI DELI NE COMMITTEE

Professional Practice Committee

#### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Vivian Fonseca, MD, Chair; Evan M. Benjamin, MD; Lawrence Blonde, MD; Kenneth Copeland, MD; Marjorie L. Cypress, MS, RN, CDE; Hertzel C. Gerstein, MD, Msc, FRCPC; Irl Hirsch, MD; Steven Kahn, MB, ChB; Elizabeth Mayer-Davis, MS, PhD, RD; James Meigs, MD, MPH; Michael P. Pignone, MD, MPH; Janet H. Silverstein, MD; Geralyn R. Spollett, MSN, C-ANP, CDE; Judith Wylie-Rossett, RD, EdD; Nathaniel G. Clark, MD, MS, RD, Staff

#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### **GUIDELINE STATUS**

This is the current release of the guideline.

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#### GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>American Diabetes Association (ADA) Website</u>.

### AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Introduction. Diabetes Care 29:S1-S2, 2006
- Strategies for improving diabetes care. Diabetes Care 29: S34-S35, 2006.

Electronic copies: Available from the <u>American Diabetes Association (ADA) Web</u> site.

The following are also available:

Diagnosis and classification of diabetes mellitus. Diabetes Care 2006 Jan; 29
 Suppl 1: S43-8. Electronic copies: Available from the <u>American Diabetes</u>
 Association (ADA) Web site.

• 2006 clinical practice recommendations standards of care. Personal digital assistant (PDA) download. Available from the <u>American Diabetes Association</u> (ADA) Web site.

#### PATIENT RESOURCES

None available

#### NGC STATUS

This summary was completed by ECRI on April 2, 2001. The information was verified by the guideline developer on August 24, 2001. The summary was updated by ECRI on January 29, 2002, April 21, 2003, March 24, 2004, July 1, 2005, and March 16, 2006.

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